

MAR 9 - 2005

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510(k) SUMMARY of SAFETY & EFFECTIVENESS*K042109*
*5113***Submitter :**

NOVACOR France
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E-mail : dgrenier@novacor.fr**Contact person :** Mrs. Dominique GRENIER – Regulatory Affairs Director**Device trade name :** DIASYS INTEGRA II**Common/Usual name:** Ambulatory blood pressure recorder**Classification name :** Blood Pressure Measurement System**Predicate devices :**

OSCAR 2 – Model 222 – SUNTECH MEDICAL INSTRUMENTS Inc. – K003004.
SENSOCOR TM DIASYS – SENSORMEDIX Inc. – K881771

Device description :

The DIASYS INTEGRA II is a non invasive automatic ambulatory blood pressure recorder. It has two standard modes of operating, the auscultatory mode and the oscillometric mode. The required mode is selected with the DiasySoft Software. If neither of these modes has been specially programmed, the DIASYS INTEGRA II will choose the most appropriate mode for the patient, according to its own criteria : this is the Automatic mode.

The DIASYS INTEGRA II weighs about 195 gr. and contains the electronic system and pneumatic inflation/deflation module. The measurements are saved and can be printed out directly in report form by a printer connected to the unit. If a computer is used, recording conditions and criteria can be set and the results of the procedure can be selected, organized, stored and printed out in a fully customised report.

The system is only for measurement, recording and display. It makes no diagnoses.

Intended use :
DIASYS INTEGRA II and DIASYSOFT INTENDED USE :

The Diasys Integra II is a non-invasive Ambulatory Blood Pressure (ABP) recorder. It measures the systolic, diastolic, mean blood pressure (BP) and the heart rate (HR). It also measures and records the patient position and the arterial rigidity (QKd) at the time of each BP measurement. The BP measurements can be performed using the oscillometric mode, the auscultatory mode or the ECG-gated auscultatory mode.

The procedure can be:

- transfert to a computer for further analysis and report printing using the DiasySoft software
- printed out directly in a report form by a printer connected to the unit
- transfert to a remote computer through a modem connected to the unit

Comparison of technology characteristics to predicate devices :
Predicate devices :

- OSCAR 2 – MODEL 222 – SUNTECH MEDICAL INSTRUMENTS Inc. ~~K003004~~
- SENSOCOR TM DIASYS – SENSORMEDIX Inc. ~~K001971~~

	Predicate devices		New device
Comparison items	Oscar 2	Diasys 200	Diasys Integra II
Indications	ABP recording	Same	Same
Design			
• Operating Mode	Oscillometric	Auscultatory	Oscillometric Auscultatory ECG-gated auscultatory
• Display result	Built-in LCD display PC software	Built-in LCD display Direct Print-out	Built-in LCD display Direct Print-out PC software
• Recording duration	250 measurements, 48 hours	250 measurements or 72 hours	200 measurements or 48 hours
• Sampling periods	3 time periods	4 time periods (adjustable)	Up to 24 time periods (adjustable)
• Interval of measurement		Adjustable from 2 to 99 minutes	<ul style="list-style-type: none"> • Adjustable from 2 to 99 minutes • Automatic adjustment to patient position
• Maximal cuff pressure inflation			Adjustable (max=270 mmHg)
• Additionnal measurements	Additionnal measurements triggered by the patient	<ul style="list-style-type: none"> • Additionnal measurements triggered by the patient • Palliative measurements 	Additionnal measurements manually <ul style="list-style-type: none"> • Triggered by the patient • Trigger on pressure criteria • Triggered on getting-up • Palliative measurements

Specifications			
<ul style="list-style-type: none"> Measurement ranges 	25 – 260 mmHg 40 – 200 bpm BP HR	30 – 290 mmHg 30 – 180 bpm	30 – 260 mmHg 30 – 240 bpm
<ul style="list-style-type: none"> BP precision 	+/- 3 mmHg		+/- 3 mmHg
Interface	PC serial cable	NO	<ul style="list-style-type: none"> PC serial cable Modem cable
PC Software	AccuWin Pro software	NO	<ul style="list-style-type: none"> DiasySoft software NovaModem software NovaMail software NovaDrive software
Main components	<ul style="list-style-type: none"> Two 1.5 AA alkaline or rechargeable batteries. Multiple cuff sizes 	Six 1.5 AA batteries 3 cuff sizes (large, standard, pediatric)	<ul style="list-style-type: none"> 1 NiMH rechargeable battery 3 cuff sizes (large, standard, pediatric) ECG-Position cable ECG electrodes Battery charger

Conclusion :

The information presented in this submission provides reasonable assurance that the DIASYS INTEGRA II ABPM recorder will perform in a safe and effective manner.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Novacor
c/o Ms. Dominique Grenier
Regulatory Affairs Director
4, Passage Saint Antoine
92508 Rueil-Mailmaison Cedex
FRANCE

Re: K042109

Trade Name: Diasys Integra II
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: February 01, 2005
Received: February 07, 2005

Dear Ms Grenier:


We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "B. Zuckerman for".

Brian D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

2042109

Device Name: **DIASYS INTEGRA II**

Indications For Use:

The Diasys Integra II is a non-invasive Ambulatory Blood Pressure (ABP) recorder. It measures the systolic, diastolic, mean blood pressure (BP) and the heart rate (HR). It measures and records the patient position and the arterial rigidity (QKd) at the time of each BP measurement. The BP measurements can be performed using the oscillometric mode, the auscultatory mode or the ECG-gated auscultatory mode.

The procedure can be:

- transfer to a computer for further analysis and report printing using the DiasySoft software
- printed out directly in a report form by a printer connected to the unit
- transfer to a remote computer through a modem connected to the unit

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number 2042109

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